

REMARKS

Claims 47-64 are in this case.

Applicant disagrees with the Examiner's summary of Howson et al, number 3 at the bottom of page 2 of the last Office Action.

Howson's Col. 6, lines 27-36 says and I quote, "Programming unit 13 includes a computer 16, preferably a general-purpose computer, that is capable of programming programmable logic unit 18 used to control operation of delivery unit 14 when placed in delivery unit 14 (as indicated in FIG.1). As also indicated in FIG. 1, by way of example, computer 16 preferably has machine program 20 connected therewith, as well as various database 22, assistive programs 24 and pharmacokinetic program 26, as needed, for programming the logic unit, as is brought out more fully hereinafter." Nowhere does Howson express a series of steps of operations that an operator should perform when using a medical machine to perform a medical function. A copy of FIG. 1 is attached.

Howson Col. 6, lines 60-68 says and I quote, "The logic cartridge contains the configurable portion of the logic path of the control unit and establishes operation thereof depending upon the contained configuration of logic gates or states in the delivery unit. Program 20 is a machine program that is used to operate computer 16, and the system transforms the user-provided information into a logic configuration suitable for operating the delivery unit in accordance with the intended delivery requirement of the user." Nowhere does Howson express an apparatus for receiving, and entering into said memory, the series of steps of the operator of said machine during the use of the machine to perform said medical function.

Col. 12, lines 13-38 says and I quote, "It is meant to be realized that the

instructions set above set forth if for purpose of illustration of how a particular logic cartridge can be programmed for a particular use according to this invention, and accordingly, this invention is not meant to be limited to the particular instruction set as set forth.

The software which runs on the general purpose computer allows safe and effective dispensing of multiple therapeutic agents in busy environments. The functional flow diagram for effecting programming of a logic cartridge is shown on FIGS. 8A through 8D. As shown, three levels of passwords are utilized, thereby limiting access to qualified individuals: six relevant databases are maintained (thus, cross-checks for safety purposes as well as comprehensive administrative record keeping are accomplished at the same time a delivery profile is designed); human decisions (operator action) must be made whenever the computer software detects a questionable or potentially dangerous condition in the design of the profile; when profile design is complete, the computer validates the profile to ensure that arithmetic, procedural, or conceptual errors have not been made; the computer allows syringe changes (for the plurality of syringes) to be coordinated (and thus results in an efficient use of time...". Nowhere does Howson express an apparatus for receiving, and entering into said memory, the series of steps of the operator of said machine during the use of the machine to perform said medical function. A copy of FIGS. 8A through 8D is attached.

Howson Col. 8, line 58-68; Col. 12, line 13-38 says and I quote, "The electronic controller 56 of control unit 50 also utilizes a read-write memory 58 (see FIG.4) within the delivery unit to record data about the actual operating history over a time period, for example, a number of days, and can include coding of date and time of day, if desired. Such data are useful for various purposes,

including diagnosing hardware problems, recording data of patient-demanded delivery events, recording data on physiologically or blood-level-controlled delivery profiles, and/or compiling data on the patient's compliance with a proscribed delivery schedule." Nowhere does Howson express an apparatus for receiving, and entering into said memory, the series of steps of the operator of said machine during the use of the machine to perform said medical function. A copy of FIG. 4 is attached.

Howson Col. 16, line 41-63 says and I quote, "The provided software may, if desired, cause the computer to look up the patient's history on the patient database to check for consistency. Again, the user may over-ride certain warnings with appropriate security precautions. The patient's records are automatically updated upon the user verification of correct entry.

The computer can be used not only to manage each of the infused drugs, but other drugs as well. It also charts the responses of the patient to therapy, or any laboratory measurements.

The computer is this utilized as far more than just a delivery unit programmer. It is a comprehensive medication management system. The user can also ask the computer to use pharmacokinetic algorithms to help derive optimum profiles for a patient. The algorithm prompts for laboratory data and may, if requested, remind the user of the correct sampling protocol.

The computer writes coded data into the logic cartridge only after the data has been verified and the delivery unit operation simulated and cross-checked against the original desired discrete flow segments using the program established by the computer to thereby insure safety of operation. The computer also then causes a label to be printed, atn appropriate pharmacy form, for placement of the

cartridge. Finally, the computer may cause a hard copy of the patient's updated record to be printed, and copies all data into the patient database." Nowhere does Howson express an apparatus for receiving, and entering into said memory, the series of steps of the operator of said machine during the use of the machine to perform said medical function.

Howson Col. 15 line 65-Col. 16, line 2 says and I quote, "the programming unit prompts the user (such as a pharmacist) for patient and prescription data. Basic protocol information may be requested from a database to speed data entry. The protocol outline ask only for the minimum amount of data needed to individualize dosages to the patient." Nowhere does Howson express an apparatus for receiving, and entering into said memory, the series of steps of the operator of said machine during the use of the machine to perform said medical function.

Howson Col. 12, line 44-66 says and I quote, "...the pump will produce for each moment in time before-hand); the output from the simulator program is compared point by point with the designed profile as maintained in each of the delivery segments by the cross-check amounts to both a check of predicted performance in the pump, as well as an overall check on the integrity of the software and the general purpose computer in which the software is running); the computer produces a hard-copy printed summary of the simulator run (this tells the human operator exactly what the pump hardware will produce hour-by-hour for the whole profile's duration and places the burden for acceptance of the computer's work on the operator's shoulders); the logic cartridge is finally programmed, or "burned", and then read back and compared with its own generating file to assure integrity: and by providing a drug administration report a simple and graphic method is provided by which the pump then seen can be

quickly compared with a piece of paper to immediately make it apparent that infusion is proceeding either properly or improperly.” Nowhere does Howson express an apparatus for receiving, and entering into said memory, the series of steps of the operator of said machine during the use of the machine to perform said medical function.

Howson Col. 15 line 60-Col. 16, line 19 says and I quote, “...sophisticated controls into small and thus compromise both size and user friendliness. In addition, the system of this invention, uses partitioning (i.e., programming in a separate unit from that of the delivery unit) which is a major departure fro known practice.

The programming unit prompts the user (such as a pharmacist) for patient and prescription data. Basic protocol information may be requested from a database to speed data entry. The protocol outline asks only for the minimum amount of data needed to individualize dosages to the patient.

Protocols are derived from published sources, third parties, or ware developed by the user. In the latter case, friendly software is preferably provided to assist the user by asking a series of questions. All protocol entries and change may be preferably date/time coded to provide a complete audit trail.”

If requested, the computer queries a drug database to check for dosage range errors and for compliance with package insert labeling.” Nowhere does Howson express an apparatus for receiving, and entering into said memory, the series of steps of the operator of said machine during the use of the machine to perform said medical function.

Dorne Col. 9, lines 53-60 says and I quote, “When reviewed examinations are billed, all examinations which have been coded by the interactive program and

reviewed by the user are sent to the billing office within the radiologist's practice. Billing reports can be sent using sheets of paper printed on a printer or via comma-delimited ASCII files that are placed on a hard drive or floppy disk. After an examination is sent to the billing office, the status changes to BILLED." Nowhere does Dorne express an apparatus for receiving, and entering into said memory, the series of steps of the operator of said machine during the use of the machine to perform said medical function.

Dorne Col. 15, lines 60 - col. 16, line 19 says and I quote, "After storing all CPT codes associated with the selected procedures in the final code system variable, the interactive program advances to an activity block 364 and groups the codes in the final code system variable into radiological codes (e.g., 70,000 codes) and non-radiological codes (e.g.) 30,000 and 90,000 codes). The interactive program then proceeds to the next activity block 368 and sorts each grouping in the final code system variable by descending RVU values. This step assures that the physician receives maximum payment for the performed procedures because Medicare and other insurance carriers compensates 100% of the fees for the first surgical CPT code listed, 50% of the fees for the next surgical CPT code listed and 20% of the fees for each following surgical CPT code. Thus, it is economically advantageous to list the CPT code having the largest RVU value first.

The interactive program preferably also has the capability of keeping track of the ICD-9 diagnostic codes most likely associated with the procedures selected by the user. Specifically, after sorting the final code system variable, the interactive program proceeds to an activity block 372 and recalls from memory all of the likely ICD-9 codes associated with the procedures that the user has selected. The ICD-9 codes are diagnostic codes specified by the International Classification

of Diseases (9th revision). The interactive program stores these codes to a ICD-9 system variable.” Nowhere does Dorne express an apparatus for receiving, and entering into said memory, the series of steps of the operator of said machine during the use of the machine to perform said medical function.

Dorne Col. 3 lines 1-15 says and I quote, “Because of the complexity of the CPT coding system outlined above, payments from Medicare and private insurance companies commonly lack parity with the physician’s services. Moreover, physicians are commonly requires to code examinations themselves because the CPT coding system demands a thorough understanding of the medical nomenclature used by the CPT code. However, coding is a time consuming task for a busy physician.” Nowhere does Dorne express an apparatus for receiving, and entering into said memory, the series of steps of the operator of said machine during the use of the machine to perform said medical function.

Prince Col. 12 line 9-36 says and I quote, “A mechanical injector is preferred because of the greater reliability and consistency when compared to injecting by hand. Since the magnetic field interferes with normal functioning of electronic devices, a pneumatic powered, spring loaded or other non-electric pump may be suitable. It should be noted, however, that as electrical pump may be used if its operation is unaffected by the operation of the magnetic resonance imaging system, e.g., if the pump is adequately shielded or if it is located sufficiently far from the magnet.

In one preferred embodiment, the mechanical infusion device 12 is coupled to the magnetic resonance imaging system 16 to facilitate proper or desired timing between the injection of the magnetic resonance contrast agent and the acquisition of the image data, in addition to providing proper or desired rates of infusion of

the contrast agent.

In another preferred embodiment, proper or desired timing and rates of infusion of the contrast agent are controlled through a control mechanism as the mechanical infusion device 12. That is, the mechanism that controls the infusion timing and rates of infusion is implemented within the mechanical infusion device 12. In this circumstance, the mechanical infusion device 12 is a “self-contained” unit.

As mentioned above, the infusion device 12 injects the magnetic resonance contrast in a strictly controlled manner.” Nowhere does Prince express an apparatus for receiving, and entering into said memory, the series of steps of the operator of said machine during the use of the machine to perform said medical function.

Howson et al has a past history not a standard series of steps of the operator to perform when the machine is being used to perform a medical function.

The standard series of steps set forth was the manager’s desirable way to do things.

Even if the combination of Howson, Dorne and Prince is made it does not meet the claims of applicant, neither Howson, Dorne nor Prince teach a predetermined series of steps of the operator of a medical machine nor place the individual series of steps of the operator of a medical machine into the computer and therefore has nothing to do with the present invention.

Even if the combination of Howson , Dorne and Prince is made they do not do what the present invention does. Subject matter of applicant claims, neither one has a predetermined series of steps of the operator to perform when the machine is being used to perform a medical function.

MPEP Sec. 2143.03 says quote:

“To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royke*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).” “All words in a claim must be considered in judging the patentability of that claim against the prior art.”

The claims in this case are different in scope from the claims in the parent application.

Claim 47 patentably defines over the prior art by calling for “a predetermined series of steps that an operator should perform when using said machine to perform said medical function,

apparatus for receiving, and entering into said memory, the series of steps the operator performed during the use of said machine to perform said medical function,

said computer including a program for comparing said predetermined series of steps with said series of steps that were entered by said apparatus.”, which is not in *Howson*, *Dorne* or *Prince*.

Claim 48 is patentable as it calls for “prices computed from the operations performed by said machine.”

Claim 49 is patentable by reason of the statements in line 2 of the claim in combination with the recitals of the parent claim.

Claim 50 is patentable as it calls for, “a plurality of machines each of which performs a medical function and in which said computer compares an actual series of steps of each said machine with a predetermined series of steps and determines any difference between said predetermined series of steps and said actual series of steps.”

Claim 51 is patentable since it calls for, “plural computers, including at least one computer for each machine so that separate operators can monitor separate patient at the same time.”

Claim 52 patentably defines over the prior art by calling for “a predetermined series of steps for operating said machine to perform a medical function,

entering into said memory the actual series of steps of said operator in operating said machine,

providing comparisons by said computer which compare said predetermined series of steps and said actual series of steps of said operator.”, which is not in Howson, Dorne or Prince.

Claim 53 is patentable since it calls for, “said computer computes prices useful for billing purposes from the operations of said machine.”

Claim 54 is patentable since it calls for plural machines in the combination of steps of claim 52.

Claim 55 is patentable since it calls for, “said computer provides information on procedures performed on each of said machines as well as summaries of the operations of all of said machines and calls for the same series of steps to be performed for the same procedure.”

Claim 56 is patentable in view of its recitals in lines 2 and 3 in combination with the steps of claims 52 and 55.

Claim 57 is patentable in view of its last three lines in combination with claim 52.

Claim 58 is patentable since it calls for “prices useful for billing purposes” in the combination of claim 52.

Claim 59 is patentable since it calls for “takes a picture” in combination of claim 47.

Claim 60 is patentable since it calls for “taking a picture” in the combination of claim 52.

Claims 61 is patentable since it calls for, “said steps of the operator are entered into said memory before said machine gathers said medical information.

Claims 62 is patentable since it calls for, “a predetermined series of steps of said operator in operating said machine with each such entry occurring prior to the next medical function being performed with said machine undertaken, and

comparing said entries into said memory with said predetermined series of steps.”, which is not in Howson, Dorne or Prince.

Claims 63 is patentable since it calls for, “a predetermined series of steps that an operator should perform when using said machine to perform said medical function,

means for receiving, and entering into said memory, the actual series of steps of the operator of said machine during the use of the machine to perform said medical function, and

means for comparing said predetermined series of steps with said actual series of steps that were entered into said machine.”, which is not in Howson, Dorne or Prince.


Claim 64 patentably defines over the prior art by calling for “at least one predetermined step of a series of steps that an operator should perform when using said machine to perform said medical function,

means for receiving, and entering into said memory, at least one of the actual steps of the series of steps of the operator of said machine during the use of

the machine to perform said medical function, and

means for comparing said at least one predetermined step of a series of steps with said at least one of the actual series of steps that were entered into said machine.”, which is not in Howson, Dorne or Prince.

Respectfully,

A handwritten signature in black ink, appearing to read "William D. Hall", written over a horizontal line.

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